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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/051,395 | 05/08/98 | MATHISON | R 024916-006 |

HM12/0203

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EXAMINER

JAMEISON, F

ART UNIT

PAPER NUMBER

1654

10

DATE MAILED: 02/03/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/051,395

Applicant(s)

Mathison, et al.

Examiner

Fabian A. Jameison

Group Art Unit

1654



Responsive to communication(s) filed on January 11, 1999 (paper #9)

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) 16-20 is/are withdrawn from consideration.

Claim(s) 11 is/are allowed.

Claim(s) 1-10, 12-15, and 21 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1654

DETAILED ACTION

Response to Restriction Requirement

Applicant's election of the invention of Group I, claims 1-15 and 21, with traverse, in Paper No. 9, received January 11, 1999 is acknowledged. However, Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement. As stated in the MPEP, "the reply by the Applicant or patent owner must distinctly and specifically point out the supposed errors in the Examiner's action and must respond to every ground of objection and rejection in the prior Office action. Furthermore, the Applicant is required to specifically point out the reasons on which he or she bases his or her conclusions that a requirement to restrict is in error. A mere broad allegation that the requirement is in error does not comply with the requirement of 37 CFR § 1.111. Thus the required provisional election becomes an election without traverse" (see MPEP § 818.03(b)).

The requirement is still deemed proper and is therefore made FINAL. Claims 16-20 are hereby withdrawn from further consideration as drawn to a non-elected invention.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in Application No. 09/051,395, filed on 5/8/98.

Art Unit: 1654

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Slootstra, et al (*Molecular Diversity* 1996, 1, 87-96).

The claims are drawn to a peptide of the formula R1-X1-X2-R2, wherein X1 is Phe, X2 is any residue (or Glu or Ala), R2 is NH₂ or an amino acid sequence X3-X4-X5, wherein X3 is an aliphatic amino acid residue having a side chain hydroxyl, X4 and X5 can be the same or different, and R2 is a sequence of 1-3 aliphatic amino acid residues, which can be the same or different.

Slootstra, et al disclose a tripeptide, Phe-Glu-Gly (page 92), which corresponds to instant application wherein R1 is NH₂, X1 is Phe, X2 is Glu, and R2 is Gly. Therefore, claims 1, 3, 4 6(b) are anticipated.

5. Claims 1, 3, 4, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkes, et al (*J. Biol. Chem.*, 1988, 263, 1821).

Art Unit: 1654

Wilkes, et al., disclose tripeptide, Phe-Ala-Gly (page 1824), which corresponds to instant application when R1 is NH₂, X1 is Phe, X2 is Ala, and R2 is Gly. The reference further teaches a tetrapeptide Phe-Ala-Gly-Gly (page 1824), which corresponds to instant application wherein R1 is NH₂, X1 is Phe , X2 is Ala, R2 is Gly, Gly and Gly-Gly. Therefore, claims 1, 3, 4 and 6 (b) are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 4, 6, 9, 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkes, et al (*J. Biol. Chem.*, 1988, 263, 1821), in view of Grant (*Synthetic Peptides: A Users Guide*, W.H. Freeman & Company, 1992, page 53).

The claims are drawn to a peptide of the formula R1-X1-X2-R2, wherein X1 is Phe, X2 is any residue (or Glu or Ala), R2 is NH₂ or an amino acid sequence X3-X4-X5, wherein X3 is an aliphatic amino acid residue having a side chain hydroxyl, X4 and X5 can be the same or different, and R2 is a sequence of 1-3 aliphatic amino acid residues, which can be the same or different. The claims further recite at least one of the amino acid residues in the D-configuration.

Art Unit: 1654

The teachings of Wilkes, et al., have been previously discussed (*vide supra*). The difference between the reference and instant application is that Wilkes, et al., do not expressly disclose any amino acid residues in the D-configuration, as recited in claims 9, 10 and 21.

Grant teaches that inversion of an amino acid's chirality from L to D, confers resistance to peptides from proteolytic enzymes (page 53, middle).

In order to confer enzymatic resistance thereby prolonging biological activity, it would have been obvious to one of ordinary skill in the art to modify the peptides disclosed by Wilkes, et al., by incorporating D-amino acid residues.

Allowable Subject Matter

7. Claims 2, 5 and 12-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following species were found to be allowable: Phe-Glu-Sar, SEQ ID NO:3, 4, 6, 8 and 9.

8. Claim 11 is allowed.

Sequence Disclosure Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Art Unit: 1654

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fabian Jameison whose telephone number is (703) 305-0509. The Examiner can normally be reached Monday through Friday from 7:00 A.M. to 4:30 P.M. A message may be left on the Examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner, Cecilia Tsang, may be reached at 703-308-0254. Papers relating to this application may be submitted to Technology Centre 1600 by facsimile. Papers should be sent via the PTO fax centre at 703-305-7401. The faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Fabian A. Jameison, Ph.D.

Application/Control Number: 09/051,395

Page 7

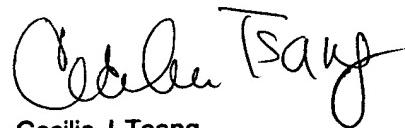
Art Unit: 1654

Patent Examiner



Art Unit 1654

January 28, 1999.



Cecilia J. Tsang

Supervisory Patent Examiner
Technology Center 1600

Application No. 09/051,395

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 O.G. 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked - up "Raw Sequence Listing."
5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

7. Other: _____

Applicant must provide:

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"
- An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification
- A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 37 CFR 1.821(f) or 37 CFR 1.821(g) or 37 CFR 1.825(b) or 37 CFR 1.825(d).

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308 - 1123

For CRF submission help, call (703) 308 - 4212

For PatentIn software help, call (703) 557 - 0400